



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/729,276	12/03/2003	Wasimul Haque	12695.13USD2	1586
23552	7590	10/27/2006	EXAMINER	
MERCHANT & GOULD PC P.O. BOX 2903 MINNEAPOLIS, MN 55402-0903			SPIVACK, PHYLLIS G	
			ART UNIT	PAPER NUMBER

1614

DATE MAILED: 10/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/729,276

Applicant(s)

HAQUE ET AL.

Examiner

Phyllis G. Spivack

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 August 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,5 and 6 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,5 and 6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>8-4-06</u> . | 6) <input type="checkbox"/> Other: _____ |

Applicants' Response filed August 4, 2006 is acknowledged. Claims 3 and 4 are presently canceled. Claims 1, 5 and 6 remain under consideration.

An Information Disclosure Statement filed August 4, 2006 is further acknowledged and has been reviewed.

Claims 1 and 3-6 were rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 6,586,414, in the last Office Action.

Following the submission of a Terminal Disclaimer, this rejection of record is withdrawn.

In the last Office Action claim 6 was rejected under 35 U.S.C. 112, second paragraph, as being indefinite with respect to the recitation "in a range".

The rejection of record under 35 U.S.C. 112, second paragraph, is withdrawn subsequent to the deletion of the recitation.

In the last Office Action all claims remained rejected under 35 U.S.C. 103 as being unpatentable over Skochii et al.; Likars'ka sprava/ Ministerstvo okhorony zdorov'ia Ukrainy. The Ukrainian document teaches the administration of pyridoxal phosphate in the treatment of cerebral stroke.

Applicants argue the correct dosage of pyridoxal phosphate in the reference is 2 gm administered intramuscularly once a day. An amendment to claim 1 now requires the administration of pyridoxal phosphate to be intravenous.

Applicants' arguments have been given careful consideration but are not found persuasive. The rejection of record of claims 1, 5 and 6 under 35 U.S.C. 103 is maintained.

The "therapeutically effective amount" recited in claim 1 is "about 0.5mg/kg to 50 mg/kg per day of the mammal's body weight." The daily intramuscular dose of 2 gm recited in the reference is encompassed in claim one. In the absence of evidence of intolerance, allergy, inflammation or toxicity, the medicinal arts generally recognize the interchangeability of intravenous and intravenous administration. Equivalent bioavailability of a particular compound is often noted. Pyridoxine is a precursor of pyridoxal-5'-phosphate; pyridoxal-5'-phosphate is an end-product of vitamin B₆ (pyridoxine) metabolism. Pyridoxal-5'-phosphate is the biologically active intracellular form of vitamin B₆, as well as in plasma. As taught by Facts & Comparisons, pyridoxine is administered by either the intramuscular or intravenous route.

The open language of claim 1 allows for the administration of any number of additional, active agents in a method of treating ischemic stroke. A reasonable expectation of success for treating cerebral ischemia or ischemic stroke follows because the therapeutic endpoint sought by Skochii is a means of neuroprotection and prevention of vessel disease in the brain through a reduction of peroxidized lipids.

An amendment to claim 1 to recite "consisting of" in place of "comprising" would obviate the rejection of record under 35 U.S.C. 103.

No claim is allowed.

Koopman-Kimenai et al., International Journal of Clinical Pharmacology & Therapeutics (abstract), is cited to show equal bioavailability of nicomorphine, as an example, in surgical patients after intramuscular administration and intravenous administration.

THIS ACTION IS MADE FINAL. Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this Final Action is set to expire THREE MONTHS from the mailing date of this Action. In the event a first reply is filed within TWO MONTHS of the mailing date of this Final Action and the Advisory Action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the Advisory Action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the Advisory Action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this Final Action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Phyllis G. Spivack whose telephone number is 571-272-0585. The Examiner can normally be reached from 10:30 to 7 PM.

If attempts to reach the Examiner by telephone are unsuccessful after one business day, the Examiner's supervisor, Ardin Marschel, can be reached 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1614

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

October 6, 2006



Phyllis Spivack

**PHYLLIS SPIVACK
PRIMARY EXAMINER**

1614